## REMARKS

The outstanding Office Action examined claims 40-56. Claims 1-39 and 57-71 were withdrawn from consideration. Applicants hereby submit amended claims 40, 41, 43-48 and 50-56, previously presented claim 42, and new claims 72-78. Claims 9, 23 and 49 have been canceled. In accordance with the Examiner's recommendation, applicants have amended withdrawn dosage form claims 1-8, 10-22, 24-27, 31 and 34.

Paragraph [0064] of the specification has been amended to correct the units of measure for the referenced surface area to recite m2/g, rather than mg/g. It is submitted that one of skill in the art familiar with the referenced Brunauer-Emmet-Teller method of measuring surface area would have understood the correct unit of measure to be m2/g.

Independent claim 40 has been amended to recite an oral dosage form, and the adsorbent has been defined as a water-insoluble, activated adsorbent which exhibits a surface area greater than 100 m2/g when measured by the Brunauer-Emmett-Teller method using nitrogen as an adsorptive material ("BET surface area"). Support for these amendments may be found in original claim 49 and Paragraphs [0064] and [0066] of the Specification.

Claim 41 was amended to more accurately state that the hydrophobic material is disposed on at least a portion of the outer surface of the adverse agent adsorbed onto the adsorbent. Claim 43 was amended to correct spelling and to delete duplication of recited compounds. Claim 47 was amended to state that the selected opioid antagonist is a different compound from the selected opioid agonist. Claim 52 has been amended to state that each listed adsorbent is in activated form. Where necessary, the claims were amended to consistently refer to an oral dosage form and to an activated absorbent.

New claims 72 and 73 depend on claim 40, and recite that the BET surface area is greater than 500 m2/g and 1000 m2/g, respectively. Support may be found in Paragraph [0064]. New claims 74-76 are each dependent on claim 40, and recite that the activated

adsorbent further exhibits an absorptive capacity as measured by adsorbance of methylene blue dye from aqueous solution of greater than 30 mg/g, 150 mg/g and 300 mg/g, respectively. Claim 77 depends on claim 76, and states that the activated adsorbent is activated charcoal and the adsorbance of methylene blue dye is measured according to ASTM D3860-98. Claim 78 is dependent on claim 76, and states that the activated adsorbent is an activated clay and the adsorbance of methylene blue dye is measured according to ASTM C837-99. Support for claims 73-78 may be found in Paragraph [0070].

**Claim Rejections Under 35 U.S.C. § 102(b)**

The Examiner has rejected claims 40, 52 and 53 under 35 U.S.C. § 102(b) as having been anticipated by U.S. Patent No. 6,353,145 to Church. As amended, each pending claim recites an oral dosage form. Church discloses a charcoal poultice which is applied to a patient's skin. There is no disclosure of an oral dosage form in Church. For at least this reason, Church does not anticipate amended claims 40, 52 or 53, and withdrawal of the rejection is respectfully requested.

The Examiner also rejected claims 40-51 and 54-56 under 35 U.S.C. §§ 102(a) and 102(e) as having been anticipated by U.S. Patent Application Publication No. 2003/0143269 of Oshlack et al. ("Oshlack1"). The Examiner cites to Paragraphs [0184], [0205] and [0206] of Oshlack1 as disclosing adsorbing an adverse agent onto an adsorbent, such as sugar spheres or microcrystalline cellulose. As amended, independent claim 40 recites a water-insoluble activated adsorbent which exhibits a BET surface area greater than 100 m2/g. The sugar spheres disclosed by Oshlack1 are water-soluble. Further, there is no disclosure in Oshlack1 that the sugar spheres are activated or have a BET surface area greater than 100 m2/g, and applicant submits that one of skill in the art would have understood that the sugar spheres did not meet either such claim limitation. Regarding the cited microcrystalline cellulose of Oshlack1, applicant submits that there is no disclosure in Oshlack1 to use a product having a BET surface area greater than 100 m2/g. Paragraph [0184] states that an

example of a suitable microcrystalline cellulose is Avicel PH-101. Submitted herewith as Appendix 1 is a copy of Yu et al., "A Staining Technique for Evaluating the Pore Structure Variations of Microcrystalline Powders", Powder Technology 98:135-138 (1998). Table 3 on page 138 of Yu sets forth the surface area of Avicel PH-101, PH-102 and PH-103 powders. Using a different measuring method, Yu reports the surface area as 1.30 m2/g, 1.26 m2/g and 1.36 m2/g, respectively. While applicant was unable to find a reported BET surface area for the Avicel products, applicant submits that Yu supports applicant's position that the BET surface area of the Avicel microcrystalline cellulose of Oshlack1 does not meet the BET surface area requirement of the presently amended claims. For at least these reasons, it is submitted that Oshlack1 does not anticipate any of the present claims.

**Claim Rejections Under 35 U.S.C. §103(a)**

The Examiner has rejected claims 40-51 and 54-56 under 35 U.S.C. § 103(a) as being unpatentable over Oshlack1 in view of U.S. Patent Application Publication No. 2003/0229111 ("Oshlack2")or U.S. Patent No. 5,846,971. The Examiner states that "Oshlack1 does not specifically teach an Example using naltrexone adsorbed onto microcrystalline cellulose" (Final Office Action page 5). The Examiner cites to Oshlack2 as teaching adsorbing naltrexone onto Avicel PH-102 in Paragraphs [0087] through [0095], and cites to Sangekar as teaching commonly used beads or spheres made of sugar or microcrystalline cellulose in column 4, lines 7-32. Applicant traverses this rejection.

As discussed above, applicant submits that Oshlack1 also does not meet the claim requirements for a water-insoluble activated adsorbent having a BET surface area greater than 100 m2/g. Osklack2 cites Avicel PH-102 as an example of a suitable microcrystalline cellulose. Yu states that the surface area of Avicel PH-102 powder, as measured by a different method, is 1.26 m2/g. Applicant therefore submits that one of skill in the art would not have understood Oshlack2 to disclose an activated adsorbent having a BET surface area greater than 100 m2/g. Regarding Sangekar, the bead materials disclosed include a number

of sugars, a number of starches, and celluloses such as microcrystalline cellulose. The example of acceptable microcrystalline celluiose given is Celphere beads from FMC Corp. Submitted herewith as Appendix 2 is a copy of a current day internet page advertising the sale of Celphere beads ( http://www.alibaba.com/product-gs/301031713/Celphere_for_Enteric_Coating_Tablets.html ) which states that the BET surface area is "> 0.100 m2/g". Applicant submits that none of the bead materials disclosed in Sangekar meet the current claim limitation of a water-insoluble activated adsorbent having a BET surface area greater than 100 m2/g.

The present claims recite an oral dosage form comprising an active agent, and an adverse agent adsorbed onto a water-insoluble activated adsorbent having a BET surface area greater than 100 m2/g, wherein at least a majority of the adverse agent is adsorbed onto the adsorbent. None of the cited references, whether taken alone or in any combination, discloses a dosage form which meets the present claim limitations. Withdrawal of the claim rejections under 35 U.S.C. § 103(a) is therefore respectfully requested.

Summary

It is respectfully submitted that claims 40-48, 50-56 and 72-78 are in condition for allowance, early notification of which is respectfully requested.

Respectfully submitted,

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